EU Declaration of Conformity

Manufacturer: Ultragel Medical Kft.
Manufacturer's address: HU 1022 Budapest Aranka utca 12.
Single registration number (SRN): SRN HU-MF-000024473
This declaration of conformity is issued under the sole responsibility of the manufacturer.

Device/s: Ultrasound gels**:**

AquaUltra Basic
AquaUltra Clear
AquaUltra Aloe
Aqua-LUB

EC Product Class: Class I in accordance with Annex VIII, Rule 1. and the above mentioned medical devices, are professionally used diagnostic and therapeutic medical device (s), which function as a medium for conducting ultrasound signals in ultrasound examinations and thus contribute to better imaging.

Manufacturer's product group: Basic-UDI-DI gels = 5996649USGEL

Declaration of Conformity

Ultragel Medical Kft. declares that ultrasound gels listed above conform to the relevant provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 .

Ultragel Medical Kft. agrees to develop, implement, maintain and certification procedure the MSZ EN ISO 13485:2016 Quality Management System to ensure continued adequacy and efficacy.

Ultragel Medical Kft. confirms that no medicinal products/drugs, tissues or cells of human or animal origin and blood derivative are incorporated in any devices covered by the Device Schedule.

Ultragel Medical Kft. agrees In Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 meets Annex 1 the General safety and performance requirements, and provides capabilities intended by the manufacturer. Under normal conditions will not endanger the patient, the operator or other person in the health and safety.

Signed by the Ultragel Medical Kft.designated representative:
Name: Szakmáry Laura
Title: Managing director
Date: 02.05.2023 V01

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